



Gender disparities in endovascular treatment options for infrarenal abdominal aortic aneurysms

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Gender disparities in endovascular treatment options for infrarenal

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“Women are less likely to be offered EVAR to correct an AAA, mainly because they have smaller arteries and the current endovascular devices are made to fit the male anatomy.”

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Objectives

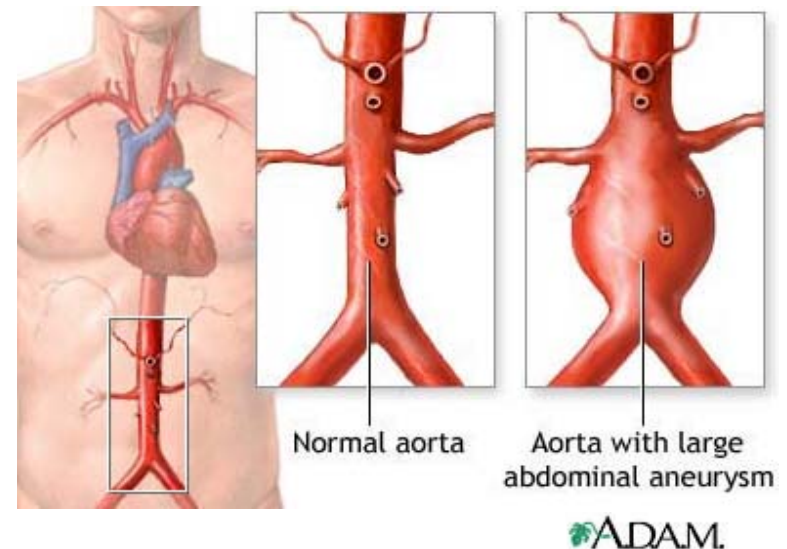
- Describe aortic aneurysm disease and how this disease presents itself differently in men and women from an anatomical perspective.
- Describe the treatment options for patients with aortic aneurysms and to highlight the gender disparities in therapies based on anatomy.
- Identify the benefits and challenges of organizing and leading a multicenter clinical research investigation that deals with patient data.

Background

- 8% of people over the age of 65 year (~ 200k annually) are diagnosed with an abdominal aortic aneurysm (AAA).¹
 - About 25% are women²

An aneurysm is a diseased, bulging, weak section of an artery wall; in this case the abdominal aorta.

- 1 in 250 persons over 50 years of age will die of a ruptured AAA.¹



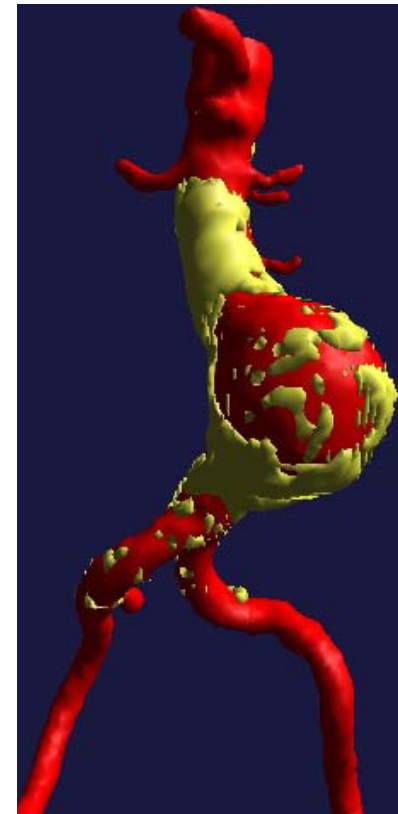
Background

Risk Factors for AAA

- The risk factors for AAA include advanced age, male gender, white race, smoking, hypertension, family history, and obesity.

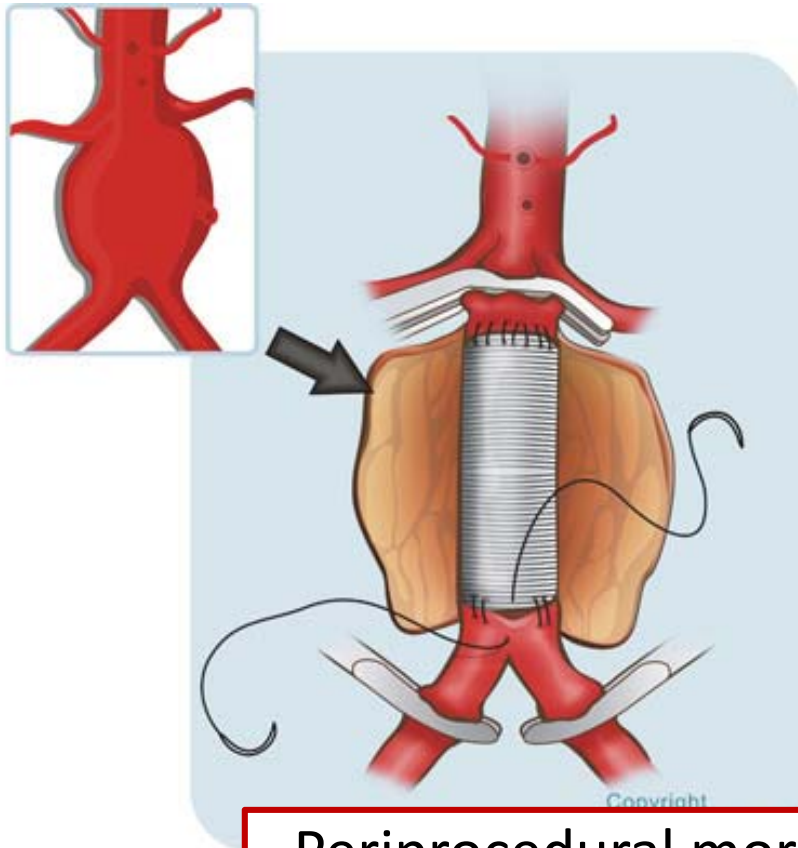
Symptoms and Risk of AAA

- AAA is usually asymptomatic, but abdominal discomfort or back pain may occur.
- The risk of AAA is rupture, associated with high mortality.

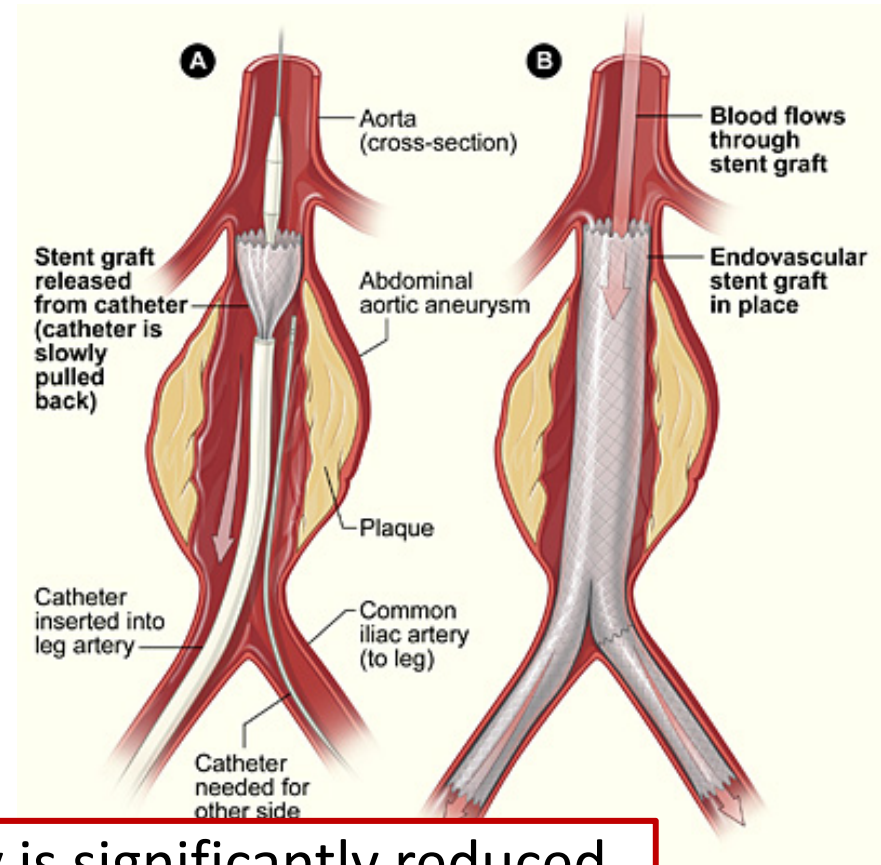


Background

Open surgical repair



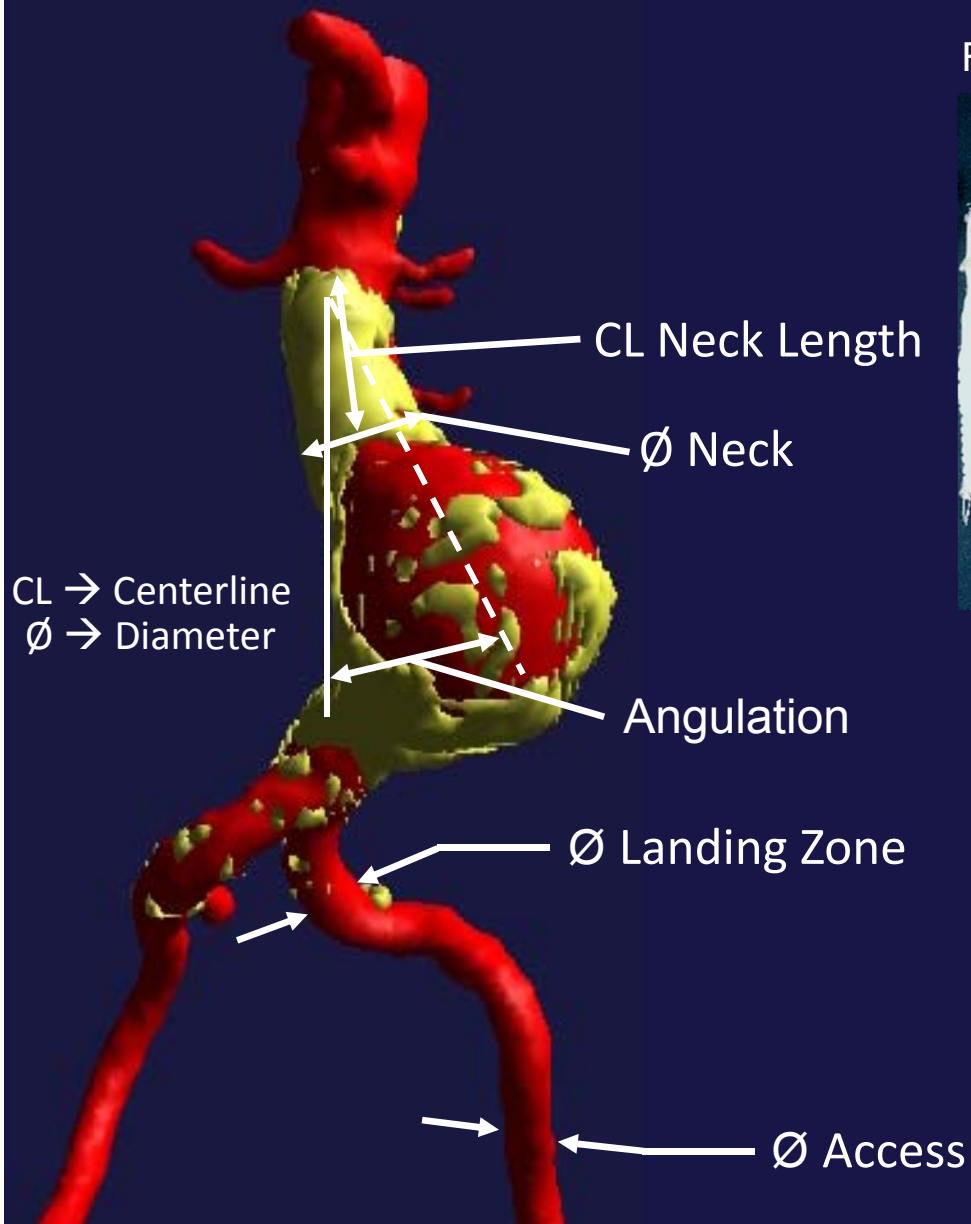
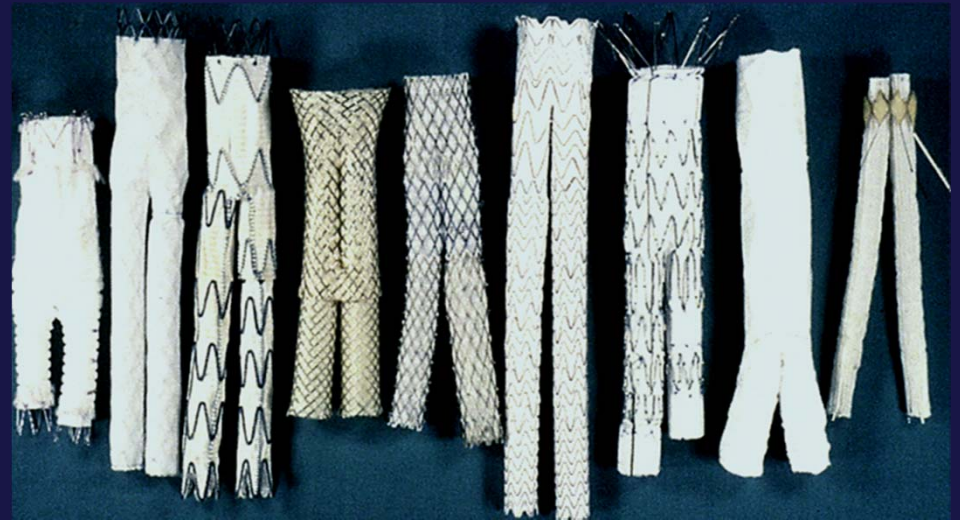
Endovascular Repair (EVAR)



Periprocedural mortality is significantly reduced with EVAR as compared to open surgical repair.²⁻³

Endovascular Grafts – up to 2009

First implanted in 1990's; first approved in US in 1999



Typical Anatomical Requirements

- Neck Length, ≤ 15 mm*
- Neck Diameter, 18 - 32 mm
- Angulation, $\leq 60^\circ$
- Landing zone, 10 - 23[^]
- Access, 5.5 - 7 mm

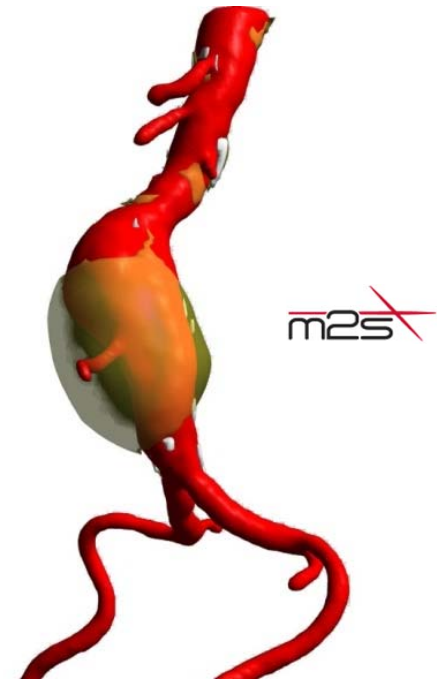
* one was ≤ 10 mm

[^] one was as small as 8 mm

CHAP Objectives



- To collect detailed, unadjusted 3D anatomic data from unbiased broad samples to better understand gender differences in anatomy for patients with AAA
- To understand ineligibility and identify gender disparities treatment options

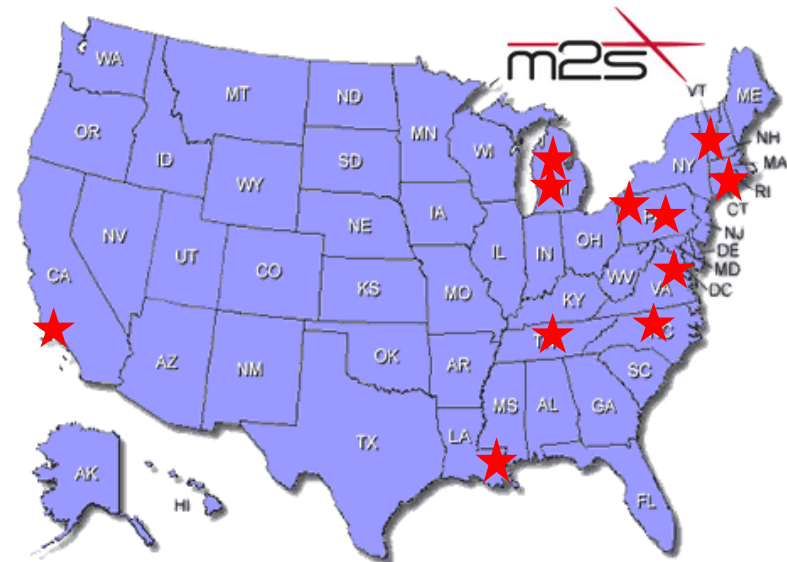


3DCT Reconstruction

Methods

We collected pre-operative CT scan data from eleven U.S. clinical centers that consecutively submit their AAA cases to M2S, Inc. for 3D anatomical analysis.⁴ De-identified data were gathered from time periods where all or nearly all cases were submitted over 16 years. Data were tested and found to be homogenous ($p = \text{NS}$).

Cardiovascular Institute of the South, LA
Dartmouth Hitchcock Medical Center, NH
Geisinger Medical Center, PA
Harbor UCLA Biomedical Research Center, CA
Massachusetts General Hospital, MA
Michigan Vascular Center, MI
Sentara Norfolk General Hospital, VA
University of North Carolina Medical Center, NC
University of Michigan Medical Center, MI
University of Pennsylvania Medical Center, PA
Vanderbilt Medical Center, TN



Methods



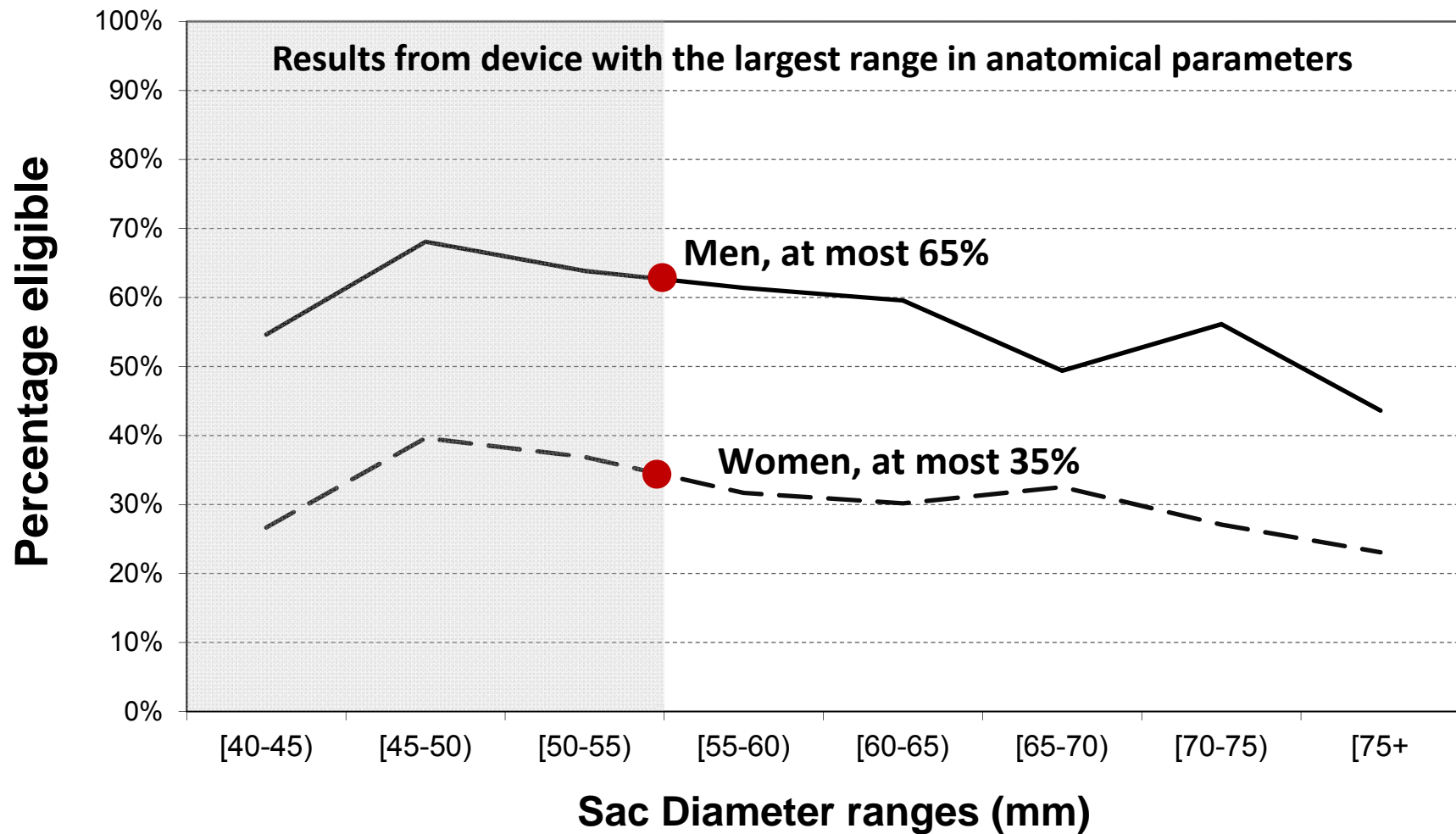
The CHAP database contains **14855 unique patients** with a variety of untreated abdominal aortic pathologies.

nearly 10k patients have an AAA

In addition to the standard anatomic parameters measured by M2S, Inc., we matched the most recent scan with the patient's year-of-birth and gender.

We compared the anatomic parameters of every man and woman to the anatomic criteria of endovascular grafts to investigate ineligibility.⁵

Eligibility – up to 2009



What is driving ineligibility?



All measurements are in mm unless otherwise noted

percentile	Women										Men										M – W		
	1	5	10	25	50	75	90	95	99	1	5	10	25	50	75	90	95	99	10	50	90		
Neck length	3	3	4	6	12	20	30	37	48	3	4	5	9	16	27	37	44	50	1	4	8		
Neck diameter	15	17	18	19	21	24	28	31	33	17	19	20	21	23	26	29	30	33	2	2	0		
Infrarenal angle, °	10	19	25	34	45	58	70	78	92	7.3	14	19	26	36	47	58	65	83	-6	-9	-12		
Suprarenal angle, °	2	5	8	13	22	33	47	58	75	2	4	6	10	17	26	36	44	61	-1	-5	-11		
Common iliac diameter	6	8	8	9	11	13	15	17	25	7.9	10	10	12	14	16	20	23	32	2	3	5		
Centerline path length from the distal renal artery to aortic bifurcation (p = NS)	88	99	105	114	125	136	148	157	174	92	102	107	116	126	138	151	159	177	2	1	3		

Median anatomy

- Neck length for Men (16 mm)
but for Women (12 mm)
- Neck angulation for Men (36°)
but for Women (45°)
- Iliac Diameter for Men (14 mm)
but for Women (11 mm)

But recall,

Typical Anatomical Requirements

- Neck Length, ≤ 15 mm
- Angulation, $\leq 60^\circ$
- Landing zone, 10 - 23

Next Generation of Devices – 2012/2013



- Three new devices and two devices with modifications⁶

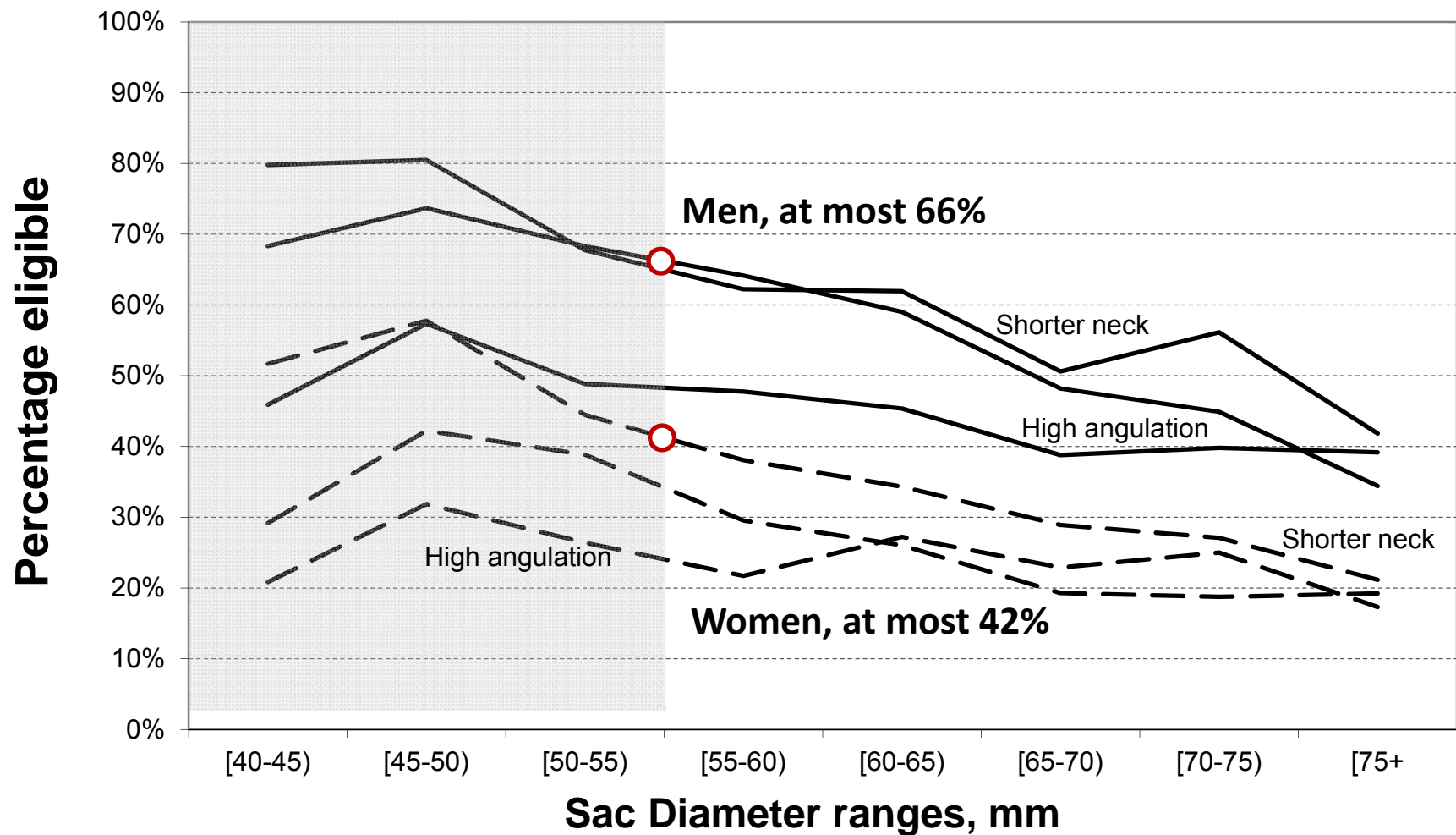
	Gore Excluder	Endologix AFX	Cook Flex ^a	Medtronic Endurant II	Cook Fenestrated	Trivascular Ovation ^b	Lombard Aorfix
Year of Release	2009	2009	2012	2012	2012	2012	2013
Neck diameter, mm	19-29	18-32	18-32	19-32	19-31	16-30	19-29
Neck length, mm	≥ 15	≥ 15	≥ 15	≥ 10	≥ 4	≥ 10 > 7	≥ 15
Infrarenal neck angulation, deg	≤ 60	≤ 60	≤ 60	≤ 60	≤ 45 ^c	≤ 60 ≤ 45 ^c	≤ 90
Iliac diameter, mm	10-18.5	8-23	8-20	8-25	7-21	8-20	9-19
Smallest delivery system OD ^d Profile, Fr	20.5	19	21	18	23	14	22

a – includes Spiral-Z, b – we included an additional anatomic criteria unique to Ovation; because the mid-line of the fill ring is 13 mm distal to the top of the graft, we also included that the diameter 15 mm below the renal artery ≤ 30 mm (for neck lengths < 15 mm) to ensure adequate sealing, which is a conservative estimate because we do not have the aortic diameter at 13 mm. c – both infrarenal and suprarenal, d – outer diameter of sheath if the device requires one.

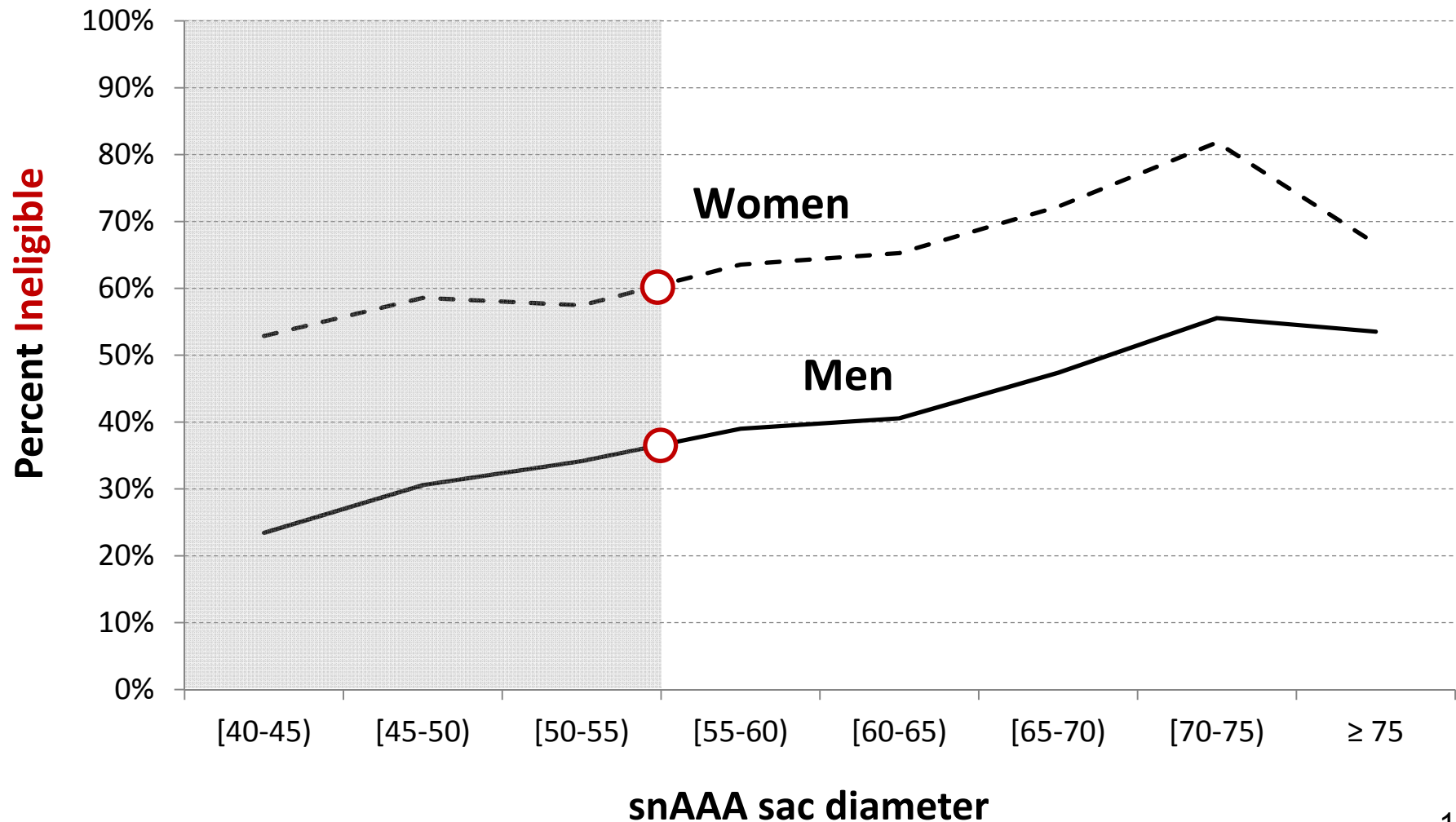
Expanded Anatomical Requirements

- Short neck lengths
- Higher angulation
- Smaller delivery system

Eligibility – up to 2013



Based solely on anatomy, nearly 35% of Men and 60% of Women are **ineligible** for EVAR in the treatment range.⁷



Conclusions

Limitation: We solely examined ineligibility based on anatomic criteria of the instruction for use – this does not necessarily reflect clinical practice or confer medical eligibility for the procedure.

- We characterized the anatomy of patients with AAA.
 - Clinically meaningful gender differences were noted in the length and angulation of the infrarenal.
- We compared the anatomic data of AAA to the IFU criteria of commercially available endovascular grafts.
 - The limiting factors are not just a short neck or an angulated neck; **it's a short, angulated neck**, especially for women.
 - No commercially available device for this anatomy

Conclusions

Nearly 35% of Men and 60% of Women are **not** eligible for EVAR with the current commercially available endovascular grafts at the current treatment threshold of 55 mm.

- Ineligibility increases with larger size AAA

References



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Acknowledgements

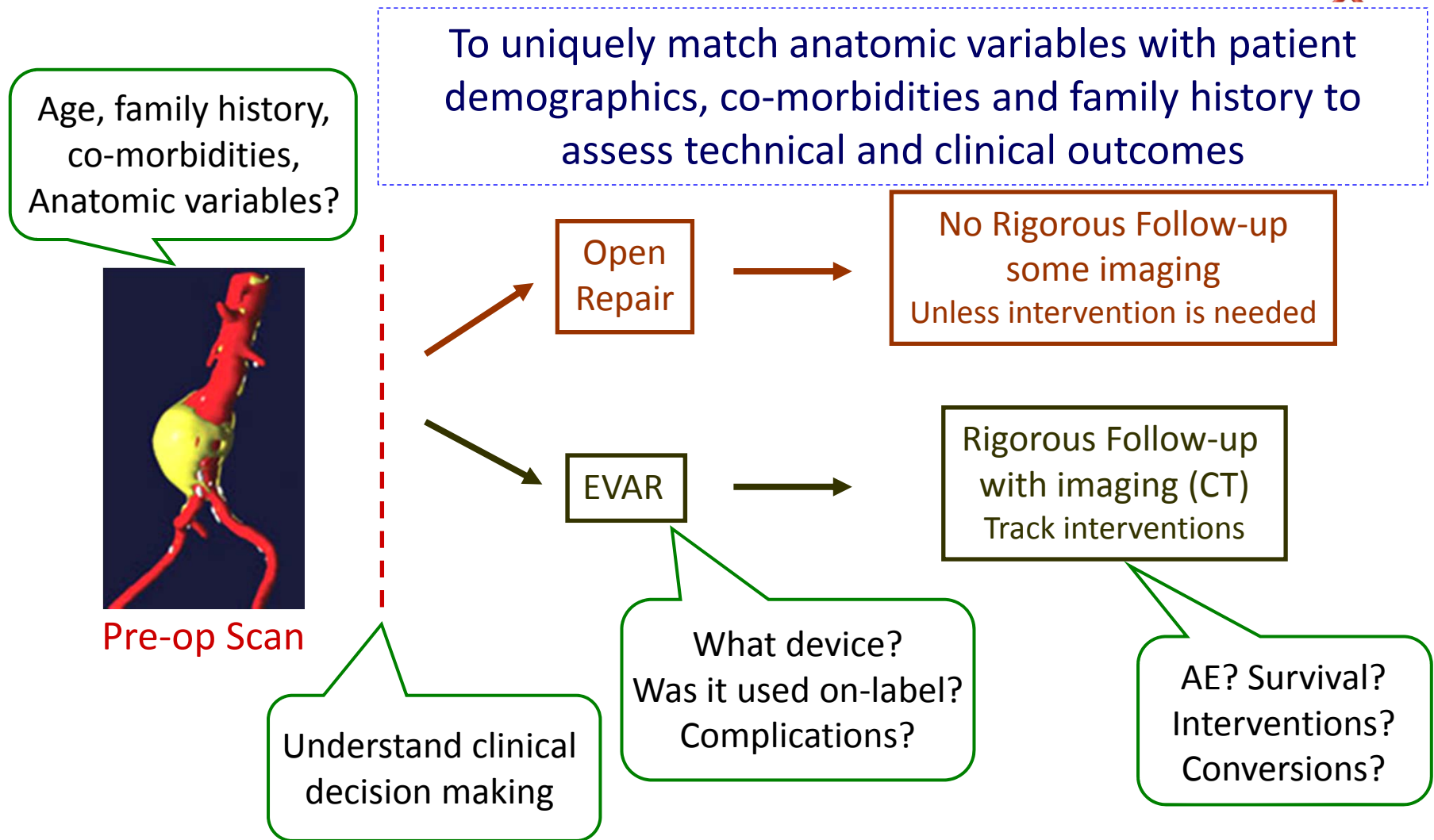


Next Steps

FDA's Office of Women's Health is funding a new study:
"Abdominal Aortic Aneurysms: analysis of patient
Characteristics and Anatomy Related to EVAR treatment
and outcomes"



AAA-CARE



Expected Impact



Current studies are either

- single-center with *minimal* assessment of anatomic contributors to outcome, or
- multi-center focused clinical success and without mention of anatomic contributors.

No study links **BOTH**. AAA-CARE is a large, multi-center study that will link together pre-operative anatomy with pre-defined demographics to assess

- percentage of patients (and women) who receive OR vs EVAR;
- understand multiple factors that contribute to treatment decision making;
- discover how many were treated with an EVG on- or off-label; and
- what were the long-term clinical and technical outcomes.

Expected Impact



- Outcomes of this study might result in helping device manufacturing to better serve women, which would result in **regulatory changes** (expanded patient eligibility for EVAR and changes to the Instructions for Use for EVG) and **evaluation parameters** (e.g., improved nonclinical testing) for next generation devices to treat AAA.
- These results may have the potential to **impact the clinical practice** of treating patients, especially women, with AAAs.



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